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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	
ART UNIT	**PAPER NUMBER**
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,632	JENSEN ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/23/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The present Office Action is responsive to the Amendment received on February 23, 3009.

Preliminary Remark

Claims 1-18 are pending and are under prosecution herein.

Information Disclosure Statement

The IDS received on February 23, 2009 is proper and is being considered by the Examiner.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to its parent claim in the alternative. presently, claim 15 incorporates limitations from both claims 13 and 14. While under normal circumstances, such claims are no longer treated on their merits, since the metes and bounds of claim 15 is, nevertheless, clear, it has been examined.

Claim Rejections - 35 USC § 112

The rejection of claims 5, 6, 13, 14, 16, and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on September 23, 2008 is withdrawn in view of the Amendment received on February 23, 2009.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, and 17 under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al.

(Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[1] ref# 56), made in the Office Action mailed on March 11, 2009 is withdrawn in view of a careful reconsideration of the rejection.

The rejection of claims 3, 4, 7-9, 13-15, and 18 under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[2] ref# 56), as applied to claims 1, 2, and 17 above, and further in view of Johns et al. (Letters in Applied Microbiology, 1994, vol. 18, pages 236-238; IDS[3] ref# 47), made in the Office Action mailed on March 11, 2009 is withdrawn in view of a careful reconsideration of the rejection.

The rejection of claims 5, 6, 10-12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[3] ref# 56), as applied to claims 1, 2, and 17 above, and further in view of Braven et al. (WO 03/074731 A2, published September 12, 2003, filed February 11, 2003; IDS[4] ref# 34).

Rejections, New Grounds

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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[1] IDS received on January 25, 2007
[2] IDS received on January 25, 2007
[3] IDS received on January 25, 2007

Claims 1, 2, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (Analytical Biochemistry, 2002, vol. 372, pages 49-65) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[4] ref# 56) and Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999).

Huang et al. disclose a MEMS-based sample preparation for molecular diagnostics, wherein the artisans expressly disclose that such systems have the advantage of, "multiplexing so that several analyses can be completed simultaneously," as well as "integrating various functional components on to the device," as well as, "unsupervised automation." (page 49, 2nd column).

Huang et al. disclose a typical method steps involved in molecular diagnostics, which involves, the steps of cell preparation/concentration, cell lysis, molecular extraction & purification, and for DNA/RNA, amplification, followed by their detection, and expressly suggest using MEMS for conducting these common steps:

> "Over the last five years, several attempts have been made to miniaturize molecular diagnostics, inclusive of sample preparation, in the area of biological warfare agents and point-of-care ... Some of these efforts involve microfluidic systems, in which the ***entire*** procedure from sample ***collection through PCR, and sometimes, all the way to detection, is embedded in one integrated instrument."*** (page 54, 2nd column, 1st paragraph)

Huang et al. refer to a device of Nanogen™, which performs, "collection of *E. coli* by dielectrophoresis, lysis of the bacterial and denaturation, DNA amplification, desalting, denaturation of the amplified/desalted amplicon, and DNA hybridization (page 55, 1st column bottom paragraph to 2nd column, 1st paragraph).

Huang et al. do not explicitly disclose that a first and second electrode is provided and that the chamber is positioned so that at least part of the sample chamber is between the first and the

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second electrode, and that a potential is applied to the first and second electrode so as to assist electrostatic collection of the biological sample into the chamber.

Huang et al. do not explicitly disclose that the distance between the first and the second electrode is at most 20 mm.

Huang et al. do not explicitly disclose that the liquid agent which forms a mixture with the contacted biological particle comprises one or more reagents required to perform a nucleic acid amplification, or that the first liquid reagent comprises one or more reagents selected from the group consisting of a primer, a triphosphate nucleotide and a polymerase.

While Huang et al. disclose a device which collects, lyses, and conducts DNA/RNA analysis on a single chip, the artisans do not explicitly state that a device comprising a first and a second electrode, a heating electrode, and a temperature sensing element, nor an apparatus configured for such a purpose.

Mainelis et al. disclose a device comprising 2 electrodes, spaced at a distance of 20 mm (page 1074, 2nd column, 2nd paragraph; page 1075, Figure 1A, height, "H"), wherein the artisans employ said device to generate an electrical field, for the purpose of collecting bacterial spores from air samples (thus gaseous; see page 1077, 1st column, 4th paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Huang et al. with the teachings of Mainelis et al., and Birmingham et al., thereby arriving at the claimed invention for the following reasons.

The motivation to arrive at a single device which conducts the steps of collecting biological spores from gaseous sample, followed by their lysis, and followed by their analysis, for the advantage of producing portable devices for military usages, has been known in the art, as clearly expressed by Birmingham et al.:

> "One of the more important applications of technology requiring the lysing of bacterial cells and/or spores is in facilitating identification of biological agents that are used during bacteriological warfare or in attacks by terrorists. In order to permit known harmful bacteria to be identified, it is important that DNA and RNA comprising the bacterial cells or spores found in the suspect environment be made available for analysis. By providing a reliable and portable apparatus for lysing bacteria cells or spores collected from the environment, it will be possible to identify bacteriological warfare agents in the field so that appropriate counteractive and protective measures can be implemented. ***A portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agents will greatly enhance the ability of civilian populations and troops to survive such attacks***." (column 2, lines 24-39, Birmingham et al.)

As discussed already above, Huang et al. disclose a method and a use of a device that collects bacterial samples, followed by the lysis of the bacterial samples, followed by the analysis of the extracted DNA/RNA therefrom.

In addition, Huang et al. expressly disclose that cells can be lysed electrically on microelectrode arrays after pulse-electric field treatment (page 53, 2nd column).

As one of ordinary skill in the art would have been motivated (as expressed by Birmingham et al.) to arrive at a device, a method of using such a device which collects bacterial spores from air samples, concentrating them, followed by their lysis and analysis, said one of ordinary skill in the art would have been reasonably motivated to employ the means offered by Mainelis et al. into the device and method disclosed by Huang et al., for the benefit of, increasing the collection efficiency of, "airborne microorganisms" (Abstract, Mainelis et al.), prior to their lysis and analysis.

Said one of ordinary skill in the art would have had a reasonable expectation of success at integrating the sample collection/concentration module of Mainelsis et al. with the device of Huang et al., as the artisans would have had the ability to combine the necessary modules to arrive at a single device performing the desired analysis, as Birmingham et al. have already evidenced. While Birmingham et al. conducted the spore lysis by an ionization discharge, the artisans clearly not only motivated a ordinarily skilled artisan to arrive at a single device which collect biological samples

from air, lyse and analyze, but also showed the feasibility of producing such an integrated device. Provided that Huang et al. expressly disclose that cells can be lysed via electrical field, which is necessarily produced between two electrodes (page 52, 2nd column, Huang et al.), said one of ordinary skill in the art at the time the invention was made would have reasonably concluded that the use of electrodes, not only to collect, but also to lyse the sample would have been possible, rendering the invention as claimed *prima facie* obvious over the cited references.

Claims 3, 4, 7-9, 13-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (Analytical Biochemistry, 2002, vol. 372, pages 49-65) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[5] ref# 56) and Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999), as applied to claims 1, 2, and 17 above, and further in view of Johns et al. (Letters in Applied Microbiology, 1994, vol. 18, pages 236-238; IDS[3] ref# 47).

The teachings of Huang et al., Mainelis et al., and Birmingham et al. have already been discussed above.

While Huang et al. and Birmingham et al. disclose that any kinds of DNA/RNA analysis could be conducted, the artisans do not explicitly disclose that a nucleic acid amplification detection should be conducted for measuring the presence of the amplified target nucleic acid, or that nested-PCR be conducted, or that a chip configured for such a purpose, or that a device which is configured for housing such a chip be produced.

Johns et al. disclose a method of detecting *Bacillus anthracic* in spores by use of PCR (Abstract).

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Huang et al., Mainelis et al., and Birmingham with the teachings of Johns et al., thereby arriving at the claimed invention for the following reasons.

Huang et al. and Birmingham et al., while not explicit in stating that a PCR be conducted for the DNA/RNA analysis followed by the spore lysis and extraction of DNA/RNA therefrom, the artisans clearly imply any type of DNA/RNA analyses available in the art could be employed:

> "Once the surface membranes of the bacterial cells and/or spores have been ruptured by lysing apparatus...,the exposed nuclear material comprising specimen…is carried by conveyer...to a spore or cell RNA/DNA identifier...This identifier processes the nuclear material to identify the specific type of bacterial cells and/or spores comprising the specimen. The device preferably used for identifying the type of bacteria in the specimen is a time of flight mass spectrometer. However, a number of other types of bacterial spore and cell identifiers might alternatively be used..." (column 5, lines 1-10, Birmingham et al.)

> "Over the last five years, several attempts have been made to miniaturize molecular diagnostics, inclusive of sample preparation, in the areas of biological warfare agents ..." (page 54, 2nd column, Huang et al.)

Johns et al. clearly demonstrate to one of ordinary skill in the art that anthrax can be identified from its spores by polymerase chain reaction (Abstract), wherein the artisans extract DNA from spores of anthrax, and conducts PCT (page 236, 2nd column).

The artisans state that the disruption of the spores prior to the PCR amplification provided faster and sensitive result (page 237, 2nd column, Johns et al.):

> "Germination of spores in PBS/150 mmol/l L-alanine/6 mmol/l OCDS prior to PCR increased sensitivity to allow for the detection of 10 spores per test. But although this procedure gave very sensitive PCR result, it was slow. As mechanical disruption might be more rapid, we decided to evaluate the use of … to mechanically disrupt spores...Equivalent sensitivity in PCRs from germinated and mechanically disrupted spores..." (page 237, 2nd column, Johns et al.).

Therefore, one of ordinary skill in the art at the time the invention was made would have clearly recognized that the use of PCR for identifying bacterial spores, wherein said spores have been disrupted, would have yielded their sensitive detection.

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success at producing the combine invention given the fact that Birmingham et al. identifies the extracted DNA/RNA from the bacterial spores by first lysing said spores. Since Johns et al. clearly demonstrate that PCR can be conducted from lysed spores of anthrax, one of ordinary skill in the art would have been motivated to combine the teachings of the artisans, thereby arriving at the invention as claimed.

With regard to the limitations drawn to the chip and apparatus, which is configured for conducting PCR (i.e., heating electrode, a temperature sensing element), it is respectfully submitted that the art is replete with miniature devices for conducting PCR, which comprises heating electrode and temperature sensing elements, and the Office is taking official notice for this teaching. Should Applicants challenge this fact, such evidence would be provided in a subsequent Office Action, but nevertheless be made final.

MPEP 2144.03(D) states the following in such a situation:

> **"If the examiner adds a reference in the next Office action after applicant's rebuttal, and the newly added reference is added only as directly corresponding evidence to support the prior common knowledge finding, and it does not result in a new issue or constitute a new ground of rejection, the Office action may be made final."**

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to arrive at the device and apparatus for conducting the method of the combined teachings of the artisans, as the motivation to conduct such a method would have been present to

said one of ordinary skill in the art, and producing a device/apparatus for such a purpose would have been well within the purview of an ordinarily skilled artisan.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claims 5, 6, 10-12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (Analytical Biochemistry, 2002, vol. 372, pages 49-65) in view of Mainelis et al. (Aerosol Science and Technology February 2002, vol. 36, pages 1073-1085; IDS[6] ref# 56) and Birmingham et al. (U.S. Patent No. 5,989,824, issued November 23, 1999), as applied to claims 1, 2, and 17 above, and further in view of Braven et al. (WO 03/074731 A2, published September 12, 2003, filed February 11, 2003; IDS[4] ref# 34).

The teachings of Huang et al., Mainelis et al., and Birmingham et al. have already been discussed above.

While Huang et al. and Birmingham et al. disclose that any kinds of DNA/RNA analysis could be conducted, the artisans do not explicitly disclose that a nucleic acid amplification detection should be conducted for measuring the presence of the amplified target nucleic acid, wherein said amplification is detected by electrochemical means, involving oligonucleotide probes which release redox active component upon their degradation, wherein the measurement of such degradation is measured by voltammetry, or that a chip configured for such a purpose, or that a device which is configured for housing such a chip be produced.

Braven et al. disclose a method and a device for probing for a nucleic acid comprising contacting a nucleic acid solution with an oligonucleotide probe labeled with an **electrochemically active marker**, providing conditions at which the probe is able to hybridize with any

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complementary (target) sequence which may be present in the nucleic acid solution, **selectively degrading either hybridized or unhybridised nucleic acid probe**, and electrochemically determining information relating to the electrochemically active marker (page 3, line 30 to page 4, line 5)

Braven et al. state that the term, "degrade" includes degradation as a result of enzyme activity, for example by digestion. (page 3, line 30 through page 4, line 5).

In a specific embodiment, Braven et al. disclose that a 5' nuclease activity of *Taq* polymerase or a similar enzyme may be used to digest a nucleic acid probe which has hybridized at a position on the target between a pair of PCR primers would be employed for detection, wherein such a case, the probe would be digested concomitant to primer extension." (page 4, lines 13-16)

Braven et al. also explicitly disclose that their present invention is based on the observation that an electrochemically active marker such as matallocene exhibits different electrochemical characteristics depending on whether or not it is attached to a nucleotide, whether or not nucleotide is incorporated into oligonucleotide or not, and the length of any such oligonucleotide." (page 5, lines 12-15).

The artisans explicitly contemplate the use of voltammetry for the detection of the markers (page 7), wherein the artisans state that such a detection step may be carried out using one or more electrodes covered by a membrane which is able to selectively exclude molecules based on one or more characteristics, such as, "characteristics selected from size, charge and hydrophobicity," that may "assist in eliminating background current arising from, for example, charged nucleic acids or undigested labeled oligonucleotide" (page 7, lines 15-19), wherein the label used for detection a ferrocene (page, lines 25-30).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Huang et al., Mainelis et al., and Birmingham et al. with the teachings of Braven et al., thereby arriving at the claimed invention for the following reasons.

Huang et al. and Birmingham et al., while not explicit in stating that a electrochemical detection of PCR be conducted for the DNA/RNA analysis followed by the spore lysis and extraction of DNA/RNA therefrom, the artisans clearly imply any type of DNA/RNA analyses available in the art could be employed:

> "Once the surface membranes of the bacterial cells and/or spores have been ruptured by lysing apparatus...,the exposed nuclear material comprising specimen…is carried by conveyer...to a spore or cell RNA/DNA identifier...This identifier processes the nuclear material to identify the specific type of bacterial cells and/or spores comprising the specimen. The device preferably used for identifying the type of bacteria in the specimen is a time of flight mass spectrometer. However, a number of other types of bacterial spore and cell identifiers might alternatively be used..." (column 5, lines 1-10, Birmingham et al.)

> "Over the last five years, several attempts have been made to miniaturize molecular diagnostics, inclusive of sample preparation, in the areas of biological warfare agents ..." (page 54, 2nd column, Huang et al.)

Braven et al. disclose that their invention of electrochemical detection of PCR products have the advantage of sensitivity and simplicity, as well as other benefits:

> "Amplification-based DNA detection methods normally utilize a range of fluorescence chemistries or radioactive labels. Frequently, target DNA to be analysed is amplified enzymatically e.g., by PCR, then visualized using a fluorescent DNA binding dye to stain DNA size-separated by gel electrophoresis." (page 2, lines 1-4, Braven et al.)

> "The application of electrochemistry to DNA detection offers potential advantages over other detection systems in terms of sensitivity and simplicity. Their portability, robustness, ease of miniaturization and potential for high volume manufacturing makes apparatus for electrochemical methods especially suitable for clinical, food and environmental diagnostics." (page 2, lines 18-21, Braven et al.)

Given the explicit statement that the method of Braven et al., allows for a sensitive and portable detection of target nucleic acids from samples, especially in environmental diagnostic, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Braven et al. with the teachings of Huang et al., Mainelis et al., and Birmingham et al. who were concerned with producing portable devices for a sensitive detection of biological agents in air samples for military purposes:

> "One of the more important applications of technology requiring the lysing of bacterial cells and/or spores is in facilitating identification of biological agents that are used during bacteriological warfare or in attacks by terrorists. In order to permit known harmful bacteria to be identified, it is important that DNA and RNA comprising the bacterial cells or spores found in the suspect environment be made available for analysis. By providing a reliable and portable apparatus for lysing bacteria cells or spores collected from the environment, it will be possible to identify bacteriological warfare agents in the field so that appropriate counteractive and protective measures can be implemented. A portable field monitoring device that includes the capability to collect, concentrate, lyse, and identify bacteriological warfare agents will greatly enhance the ability of civilian populations and troops to survive such attacks." (column 2, lines 24-39, Birmingham et al.)

One of ordinary skill in the art at the time the invention was made would have been clearly attracted and thus motivated to combine the teachings of Braven et al. which allows for portable devices of sensitive detection, with the method and device taught by Huang et al., Mainelis et al., and Birmingham et al., which would have regarded portability and sensitivity of detection their high priority in successfully detecting bacteriological warfare agents in combat fields.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is

appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/590,630, made in the Office Action mailed on September 23, 2008 is maintained for the reasons already of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a method and device/apparatus which is drawn to the detection of biological particle (i.e,. spores) by binding biological particles from spores and extraction of biological material (i.e., nucleic acids) by application of electrical field, followed by the analysis of the biological material from the bacterial spores.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants state that a T.D. will be filed upon notation of allowable subject matter (page 17, Response).

Since no T.D. has been filed to date, the rejection is maintained for the reasons already of record.

The rejection of claims 1-18 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/590,768, made in the Office Action mailed on September 23, 2008 is maintained for the reasons already of record.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the same reasons discussed immediately above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants state that a T.D. will be filed upon notation of allowable subject matter (page 17, Response).

Since no T.D. has been filed to date, the rejection is maintained for the reasons already of record.

Conclusion

No claims are allowed.

Applicant's arguments with respect to the previous rejections of record have been considered but are moot in view of the new ground(s) of rejection.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 9:00 a.m. to 5:30 p.m (M-F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
5/19/2009

/YJK/